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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/826,028

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Russell A. Houser

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EXAMINER

YABUT, DIANE D

ART UNIT

PAPER NUMBER

3734

MAIL DATE

DELIVERY MODE

05/11/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/826,028

Applicant(s)

HOUSER ET AL.

Examiner

Diane Yabut

Art Unit

3734

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 54,59-68,77-89,94-102,107-120,129,154-161 and 163 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 54,59-68,77-89,94-102,107-120,129,154-161 and 163 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 January 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>3/22/07; 7/19/04</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group II (Claims 54-130, 154-161 and 163) and Species 5 in the reply filed on 19 April 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. Claims 1-53, 55-58, 69-76, 90-93, 103-106, 121-128, 130-153, and 162 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 19 April 2007.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000.

Art Unit: 3734

Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

4. Claims 54, 59-64, 66-68, 79-86, 88-89, 95-99, 102, 108-110, 112, 115, 119-120, 129, 154-160, and 163 are rejected under 35 U.S.C. 102(e) as being anticipated by **Murphy** (U.S. Patent No. **6,681,773**).

Claims 54, 59-61, 79-83, 89, 95-97, 102, 108-110, and 129: Murphy discloses a one member, substantially cone or monolithic shaped collapsible (or compressible) and expandable shaper **280** made of a compliant material that is inherently resistant to permanent deformation and configured to expand without inflation, wherein said device is shaped to define or conform more closely to a more idealized or natural shape of a heart chamber which helps prevent the result of a chamber that is too small, and when the shaper is in a substantially expanded state, it is configured to fit snugly and temporarily within a heart chamber during a surgical procedure and partially encloses an interior space such that fluids may flow freely within and without (Figures 2g-2h, col. 8, line 45 to col. 9, line 23).

Claims 62-64, 66, 84-86, 88, 98-99, and 115: Murphy discloses a means for releasing (wherein "releasing" is interpreted as being released from a collapsed or compressed position) and expanding said shaper **280** comprising an internal shaft **282** and an external shaft **296** configured such that relative movement of said shafts causes said shaper to expand, and shaper can be expanded to more than one size by continuing to move the inner shaft forward, or the length of the internal shaft opposite the shaper

Art Unit: 3734

becomes lengthened as well as be released (from a collapsed position) and self-expand after placement into a heart chamber (Figures 2g-2h, col. 9, lines 1-23)

Claims 67-68 and 119-120: Murphy discloses the shaper comprising nitinol, or a superelastic or shape memory material (col. 8, lines 45-52).

Claims 154-160 and 163: Murphy discloses a shaper **280** configured to define a more optimal shape of a heart chamber, wherein said shaper comprises one or more guide marks represented by elements **292a-e** or **294a-e** configured to aid the practitioner in positioning the shaping device or placing a suture line or selecting an appropriately sized patch, as well as one or more recessed areas (in between the marks) configured to avoid damage to anatomical structures, and the shaper comprising a compliant material configured to self-expand and does not require inflation (Figures 2g-2h, col. 8, line 45 to col. 9, line 23).

Claim 112: Murphy discloses shaper **250** comprising more than one layer **252, 254** (Figure 2e).

Claim 161: Murphy discloses a shaper **230** (balloon) with guidemarks **232a-l** that requires inflation (Figure 2d).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 65, 87, 101, and 116-117 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Murphy** (U.S. Patent No. **6,681,773**) in view of **Stevens** (U.S. Patent No. **5,797,960**).

Claims 65, 87, 101, and 116-117: Murphy discloses the claimed device except for the external shaft comprising an endoscope, and moving the shaper relative to an outer sheath causes the shaper to expand.

Stevens teaches a device for intracardiac procedures comprising an external shaft or outer sheath **133** comprising an endoscope **121** and moving a shaper **132** relative to the outer sheath causes the shaper to expand (Figure 8B, col. 17, line 65 to col. 18, line 10). It would have been obvious to one of ordinary skill in the art at the time of invention to provide an external shaft comprising an endoscope and for moving a shaper relative to an outer sheath, as taught by Stevens, to Murphy in order to allow for video imaging and remote viewing of the interior of the heart and to facilitate the expansion of the shaper by using a simple and effective mechanism that doesn't require the introduction of an inflation medium for expansion.

Art Unit: 3734

7. Claims 77-78, 94, 107, and 113-114 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Murphy** (U.S. Patent No. **6,681,773**).

Claims 77-78, 94, 107, and 113-114: Murphy discloses the claimed device except for the shaping device comprising a material that is substantially translucent or not translucent, or a color that contrasts with the natural color of cardiac tissue to make it more visible. It would have been obvious to one of ordinary skill in the art at the time of invention to provide a translucent or non-translucent colored material for the shaper, since it was well known in the art to modify the color of a device for increased visibility within a surgical site or to distinguish the device from other surgical devices.

8. Claims 100 and 111 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Murphy** (U.S. Patent No. **6,681,773**) in view of **Gershony** (U.S. Patent No. **5,383,896**).

Claims 100 and 111: Murphy discloses the claimed device except for a vacuum being used to collapse the shaper for insertion or removal.

Gershony teaches a vacuum or syringe being used to collapse a shaper, or balloon for insertion or removal (col. 3, lines 57-63). It would have been obvious to one of ordinary skill in the art at the time of invention to modify Murphy, who discloses an embodiment that requires inflation in Figures 2a-2f, with Gershony who teaches a syringe used to collapse a shaper or balloon, since it was well known in the art that vacuums or syringes are commonly used to effectively introduce or remove inflation media from shaping devices or balloons for inflation/deflation.

Art Unit: 3734

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diane Yabut whose telephone number is (571) 272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571) 272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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MICHAEL J. HAYES
SUPERVISORY PATENT EXAMINER